EPA ROLE IN KENNEDY KRIEGER INSTITUTE REPAIR AND MAINTENANCE STUDY

CONTRACTUAL HISTORY

On December 13, 1989, Kennedy Krieger Institute (KKI) submitted a pre-application to EPA for grant support for the Repair and Maintenance (R&M) Study[1]. The KKI proposed to conduct an epidemiologic study (a) to characterize exposure to lead in residential dust across a range of housing types and conditions, including particle sizing and (b) to evaluate the effectiveness of alternative R&M interventions of reducing residential sources of lead in paint and dust. The R&M interventions proposed for this study would be funded from Maryland Department of Housing and Community Development. KKI was seeking resources for the evaluation of short-term and long-term changes in children's blood lead and house dust-lead levels, and for the testing of soil and water as needed. KKI proposed to begin the study in 1990 while resources exist to implement abatement under Maryland's financing program.

In 1990, HUD estimated that 57 million privately owned and occupied U.S. housing units contain some Pb-containing paint[2]. Families with children under the age of seven years occupied an estimated 10 million of these dwellings. At highest risk were children in the nearly 4 million houses with deteriorating paint and elevated dust-lead levels. At that time, EPA was interested in a less costly and potentially more cost-effective Repair and Maintenance (R&M) interventions to reduce exposure to lead (Pb) in residential house dust and paint which in turn should reduce Pb in children's blood. Low-cost R&M study may provide a practical means of reducing lead exposure for future generations of children who will continue to occupy older housing which cannot be fully abated or rehabilitated without substantial subsidy. This work was important because lead-containing house dust, soil and residential paint had been identified as major pathways and sources of Pb in children's blood via the hand-to-mouth route of ingestion.

In 1990 EPA contracted with Battelle, which subcontracted to the Kennedy Krieger Institute (KKI), for the conduct of the R&M Study[3]. Concurrently KKI received financial support from the State of Maryland for the abatement activities, including the operation of pilot abatement projects in the City of Baltimore. In September 1991, KKI independently received a letter of commitment from the Maryland Department of Housing and Community Development to reserve funds in the aggregate principal amount of $225,000 for the R&M interventions in 75 Baltimore City Dwellings (Quality Assurance Project Plan for KKI R&M Study, July 1992, Appendix A[4].)

Given the opportunity of getting an excellent jump start due to the then ongoing KKI-Maryland collaborative R&M activities at the State and local levels and potential cost saving, EPA contracted with Battelle for planning and conducting both a pilot study and a main study of the R&M project with the following objectives:

- To evaluate the short-term (6 months) and long-term (beyond six months) changes in children's blood lead and house dust-lead levels, and for the testing of soil and water as needed.

- To aid the development of a health-based meaningful dust-lead standard in response to Congressional mandates within Title X, §403 of TSCA.

Table 1 shows the contractual history of the R&M Study. The cost corresponding to each contractual period or aggregate of periods from May 1990 to February 1993 is shown in the last column of Table 1[5].

TABLE 1. CONTRACTUAL HISTORY OF REPAIR AND MAINTENANCE with KKI Under Battelle Contract

R&M ACTIVITIES	DATE	COST, $
Planning for R&M interventions, Meeting with HUD, City and State Agencies, Lead Abatement Specialists and Private Contractors, Sample Collection and Chemical Analytical Methods Development, Design and Preparation of QAPjP for the R&M Pilot Study	May 1990 to May 1991	253,110
Formal Classroom and Field Training For Full R&M Study, Methods Modification, Pilot Reports Preparation, Mini-study of Microwave Lead Digestion	May 1991 to Dec 1992	487,413
Preparation of Full R&M Study, Cyclone Vacuum Sampler Development and Mini-Study	March 1992 to Feb 1993	484,760
	Total	1,225,283

In October 1993 KKI was awarded a separate $4.4 million contract by EPA/OPPT under Contract # 68D40001 for a period October 1993 through 1997[6].

STUDY DESIGN

As mentioned above, the study was designed to (1) characterize and compare the short-term and longer-term efficacy of alternative low cost R&M interventions which KKI had proven to be effective in reducing children's exposure to contaminated house paint, dust, soil and water, and thereby reducing children's risk to lead poisoning, (2) evaluate the efficacy of Pb-paint abatement performed according Maryland regulations and compare to that of three levels of R&M interventions in older Pb-painted dwellings in this study, and (3) aid the development of a health-based meaningful dust-lead standard.

The study design for the main study underwent EPA internal review and external peer review[7]. Staff from the Centers for Disease Control and EPA's Research and Development were among the reviewers. A Quality Assurance Project Plan (QAPjP) for the study was approved by both EPA OPPT and KKI Quality Assurance Officers[8]. The design was presented at numerous professional conferences sponsored by American Society for testing Materials (ASTM), the Environmental Information Association (EIA), the Forum of State and Tribal Toxic Agencies (FOSTTA),and LeadTech. The QAPjP was complete in July with subsequent revision at the end of December 1992[9]. On-going recruitment and enrollment activities started soon after the approval of the QAPjP.

The proposed intervention and evaluation techniques and approaches had been reviewed and concurred upon by many Offices within EPA, many Federal Agencies involved with the Interagency Task Force of Lead which EPA co-chaired with HUD, and OMB, through the approval of the Information Collection Request (ICR) for this study[10].

The work plan in the QAPjP included final preparations for the full-scale sampling of house dust, soil and drinking water, enrollment activities, environmental field sampling and chemical analysis of samples, collection and analysis of blood samples, and interim reporting. KKI conducted a training session[11] for the sampling collection phase of this program for the full-scale field activities soon after the QAPjP had been finalized and signed.

COORDINATION AND INVOLVEMENT OF PRIVATE, CITY AND STATE SECTORS

During the commencement of the study, KKI coordinated with the Enterprise Foundation, its affiliate City Homes Inc., the Maryland Department of Housing and Community Development (DHCD), the Baltimore City Health Department, the Maryland Department of the Environment to initiate the (R&M) interventions. KKI also had an agreement with City Homes, which owned and managed approximately 200 low-income rental units in Baltimore city, to be the primary source of study dwellings to receive the R&M interventions[12]. City Homes was selected because it was the most cost-effective to carry out the R&M study: the R&M work, a tenant education program, and a program of testing for lead in children's blood and in house paint were all components of the lead poisoning prevention policy adopted by City Homes in 1991. The contractor sought assistance from Baltimore City Health Department or other local health

authorities to gain access to the R&M dwellings if needed.

THREE GROUPS OF HOMES IN THE STUDY

The study was designed so that all participating family in every three groups, consisting five categories of homes, would benefit equally from living in safer housing than required by then-federal, state, or local law. There were no legal requirements for lead paint hazard intervention or prevention at the time the project started.

KKI conducted characterization and comparison of both short-term and long-term efficacy of five categories of homes for reducing levels of lead in house dust and blood in children, six months to four years of age:

(1) Previously comprehensive abated by the City Homes (first category.)

This category consisted of houses that were abated by the City under a local government program, and every known intervention had been employed to make these homes as safe as possible.

(2) Three levels of R&M homes (second-fourth categories.) The elements of interventions of each category are described in Table 3 below

(3) Post-1978 urban homes (fifth category.)

Homes built after 1978 were presumably free of lead-based paint, but were located in neighborhoods known to have high risk houses. It was known that lead poisoning could occur outside the home due to other sources, such as other leaded homes, leaded dust in playgrounds, etc.

It is extremely important to emphasize that the Study did not include a control group of families living in properties with unattended lead hazards. KKI believed the inclusion of such a control group to be unethical.

Table 1 shows the number of homes in each of five study categories[14]. Table 2 provides a summary of data collection activity by study group[15]. Table 3 compares the elements of R&M Level I through III interventions[16].

TABLE 1. NUMBER OF DWELLINGS PLANNED FOR RECRUITMENT BY STUDY GROUP

Study Group		Number of Homes
Previously Abated		15
Repair and Maintenance	Level I	25
	Level II	25
	Level III	25
Post-1978 Urban Homes		15

TABLE 2. DATA COLLECTION CAMPAIGN BY STUDY GROUP

Study Group	Months of Follow-up									number of visits
	Pre	Post	Enroll	1	2	6	12	18	24	
Abatement[a]			x			x	x	x	x	5
R & M I, II, III	x	x		x	x	x	x	x	x	8
Modern Controls			x			x	x	x	x	5

a. Enrollment was done at a point in time 2 to 3 years post-abatement.

TABLE 3. COMPARISON OF ELEMENTS OF R&M INTERVENTION LEVELS I-III

ELEMENT OF INTERVENTIONS	R & M LEVEL I	**R & M** LEVEL II	R & M LEVEL III
TESTING	Use paint test results, if any to develop the R&M plan. If no results available, assume lead-based paint (LBP) is present	Test for the presence of lead-based paint (LBP) on interior and exterior surfaces. Use results to develop the R&M plan.	Test for the presence of lead-based paint (LBP) on interior and exterior surfaces. Use results to develop the R&M plan.
FLOOR TREATMENTS	In all units, place textured walk-off mat at main entrance.	If LBP, provide floor covering. If not LBP, make smooth and cleanable. Place textured walk-off mat at all front and rear entrances. In occupied units, treat floors to extent possible.	If LBP, provide floor covering. If not LBP, make smooth and cleanable. Place textured walk-off mats at all front and rear entrances.
TRIM COMPONENT TREATMENTS	If LBP, or test results unavailable, remove loose and peeling paint on all interior surfaces, and on exterior surfaces to limit of budget. Repaint treated components.	If LBP, remove loose and peeling paint on interior surfaces, and on exterior surfaces to limit of budget. Repaint treated components. If not LBP, make interior surfaces smooth and cleanable.	If LBP, seal, encapsulate, or enclose interior surfaces and exterior surfaces smooth and cleanable.
STAIRWAY TREATMENTS	None	If LBP,encapsulate treads and risers, at minimum. If not LBP, make smooth and cleanable.	If LBP, enclose treads and risers using durable materials. If not LBP, make smooth and cleanable.
WINDOW TREATMENTS	Install well caps. Prepare and repaint all exterior window trim. Repaint interior stool with non-flat paint.	If LBP, treat in-place to reduce friction. Stabilize exterior trim. Install well caps. Repaint interior sill with non-flat paint. If no LBP, make smooth and cleanable.	If LBP, replace window and abate exterior trim. If not LBP, make smooth and cleanable.

DOOR TREATMENTS	Same as COMPONENT TREATMENTS.	If LBP, rework interior and exterior doors to reduce friction. Remove peeling paint. Repaint treated surface. If not LBP, make smooth and cleanable.	If LBP, rework interior and exterior doors to reduce friction. Remove peeling paint. Follow with use of sealants or encapsulant. If not LBP, make smooth and cleanable.

TABLE 3. COMPARISON OF ELEMENTS OF R&M INTERVENTION LEVELS I-III (Continued)

ELEMENT OF INTERVENTIONS	R & M LEVEL I	R & M LEVEL II	R & M LEVEL III
WALL TREATMENTS	Same as TRIM COMPONENT TREATMENTS.	If LBP and <25% of component is damaged, repair damaged area and seal component, at a minimum. If LBP and >25% of component is damaged, repair damaged area and treat by use of flexible encapsulant or rigid enclosure. If not LBP, clean only.	If LBP and < 25% of component is damaged area and encapsulate, at a minimum. If LBP and > 25% of component is damaged, then treat by use of flexible encapsulant or rigid enclosure. If not LBP, clean only.
FINAL CLEAN-UP	HEPA vacuum all horizontal surfaces and window components (ceiling excluded). Then wet clean horizontal surfaces.	HEPA vacuum all surfaces excluding ceilings. Then wet clean horizontal surfaces only.	HEPA vacuum all surfaces excluding ceilings. Then wet clean horizontal surfaces only.
CLEANING KITS	Provide cleaning kits to occupants for use after R&M work is completed.	Same as LEVEL I	Same as LEVEL I
EDUCATION	Provide educational materials about lead poisoning to occupants and property owners. Property owner education includes at least one walk-through of one property to review treatments and future maintenance needs.	Same as LEVEL I	Same as LEVEL I

TREATMENT OF FURNISHINGS	Clean tenant's rugs and drapes off-site to limit of budget with a signed permission, and a disclaimer.	Clean tenant's or first occupant's rugs and drapes off-site to limit of budget with a signed permission, and a disclaimer.	same as LEVEL
APPROXIMATE COST, $	1,650	3,500	

R&M LEVELS OF INTERVENTION I-III [9, 16]

- KKI's earlier research showed that all three levels of intervention reduced lead dust by approximate 80% from that found in untreated properties in Baltimore's low-income, high risk neighborhoods.

- The Maryland Department of Housing and Development ("MDHD"), as part of the State Residential Lead Paint Abatement Program, committed funds to make loans available to owners whose properties underwent lead paint repair and maintenance.

- MDHD made loans available to owners of R&M Properties who rented to low-income families and to owners of R&M Properties who themselves were low income.

- About half of the R&M Properties were occupied before the improvements to the R&M Properties were made. The first group of homes were fully occupied by families. Approximately one half of the second group of homes were occupied and none of the third group of homes was occupied.

- The highest level of abatement was done in the third level of homes, i.e., the non-occupied residences, because the work to accomplish this level of abatement created even greater risks in occupied units.

- Each of the R&M Properties received an intervention designed to lower the exposure to lead.

It is unlikely that this intervention would have occurred in these houses without the Study because there were no requirements for property owners to proactively reduce lead exposure in their rental properties.

These interventions provided the immediate benefit of a safer home to the families occupying the houses in the Study. (As noted above, about half of the families did not move into the R&M Properties to be part of this Study as they already had been living in their houses which then were not lead reduced. The remainder of families were enrolled in the Study when they moved into the vacant R&M Properties which had received extensive hazard control treatments and clearance

testing.)

SAFEGUARDS AND GUIDELINES INVOLVING HUMAN SUBJECTS FOR THE STUDY

The following is a list of safeguards and guidelines involving human subjects in the study[9,16,17]:

- signed consent forms,
- received free periodic blood lead testing which was more frequent than recommended by healthcare providers and much more frequent than experienced in the population
- received free transportation to the KKI clinic to ensure that blood lead testing was done
- received free cleaning supplies for the study homes and were encourage to use them,
- received small payments and tokens for their time doing interview with researcher.
- received results of lead and blood lead testing, and
- received free lead-safety education and literature (e.g., EPA's *Lead in Your Home* pamphlet.)
- The Study called for follow-up by KKI researchers if there were an increase of 5 or more micrograms per deciliter (µg/dl) in lead blood levels or if a blood lead level reached 20+ µg/dl. These follow-up procedures included contacting the health care provider and the Health Department, visual inspection of the home, advice to the landlord on repair if obvious deterioration was noted, and advice on cleaning and diet. These interventions were greater than those these children would have received without the Study and likely would not have occurred without the Study.
- In EPA's Solicitation/Contract form, Section H.6 Protection of Human Subjects (EPAAR 1552.223-70) (Apr 1984), it was clearly stipulated that:

  The Contractor shall protect the rights and welfare of human subjects in accordance with the procedure specified in its current Institution Assurance on file with the Agency. The Contractor shall certify at least annually that an appropriate institutional committee has

reviewed and approved the procedure which involve human subjects in accordance with the applicable Institutional Assurance accepted by the Agency, and

The Contractor shall bear full responsibility for the proper and safe performance of all work and services involving the use of human subjects under this contract,

- EPA/OPPT received Letters of approval of human subjects for each year of study from The Johns Hopkins University School of Medicine and The Johns Hopkins Hospital joint Committee on Clinical Investigation.

STUDY RESULTS[18]

- All three levels of R&M intervention were associated with statistically significant reductions in house dust lead loadings and total dust loadings that were sustained below pre-intervention levels during the two years of follow-up.

- Dust lead concentrations were significantly reduced following intervention in R&M II and III, but not in R&M I.

- Using all five groups in longitudinal data analysis, a statistically significant relationship was found between a composite measure of house dust in an entire house and children's blood lead concentration, controlling for age and season.

- Children with pre-intervention blood lead concentration equal or greater than 20 micrograms/deciliter (μg/dl) had statistically significant reduction in blood lead concentration during the follow-up, after controlling for age and season, but not in blood lead level already less than 20 μg/dl.

References:

1. Letter from the KKI to Dave Schultz, December 13, 1989.

2. Comprehensive and Workable Plan for the Abatement of Lead-Based Paint in Privately Owned Housing: Report to Congress. US HUD, December 7, 1990.

3. Letter from Phil Robinson to Holly Powell and Sue Miller, August 24, 1993.

4. Reference 9, Appendix A.

5. Contractual History (see reference 3.)

6. Actual expenditure was $4.2 million. Source: RTP-FMC Payment Official for R&M Study, Phyllis Lang, 919-541-1076, 09/05 /01.

7. Battelle Memorial Institute, Contractor for the Repair and Maintenance Study, 1992.

8. Signature page, reference 4.

9 Quality Assurance Project Plan for the Repair and Maintenance Study, July 92, Approved by EPA QA Manger December 12, 1992.

10. Information Collection Request (ICR) #1603.

11. Lead Paint Abatement and Repair and Maintenance Study Training Package, Kennedy Krieger Institute, August 10, 1992.

12. Reference 9, Revision 3, Chapter 2. 2.3.1.1, Appendices A&G..

13. Reference 9, Revision 3, Chapter 2, page 24.

14. Reference 9, page 25.

15. Reference 9, page 58.

16. Fact Sheet on the Repair and Maintenance Study: www.hopkinsmedicine.org/lead.htm

17. Monthly Progress Report for the Lead Paint Abatement and Maintenance Study in Baltimore, 1995.

18 Lead-Based Paint Abatement and Repair and Maintenance Study in Baltimore: Finding Based on Two Years of Follow-up, EPA 747-R-97-005, December 1997.